REMARKS/ARGUMENTS

Claims 1, 19-21, and 23-36 are pending. Claims 2-18 and 22 were previously canceled. All pending claims stand substantively rejected. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Detailed Action.

Expert Declaration under 37 C.F.R. §1.132

Enclosed herewith is a Rule 132 Declaration from A. Edward Osawa. As further discussed below, this Declaration presents sufficient facts to overcome the outstanding rejections.

First Rejection Under 35 U.S.C. §102

¶1. Claims 1, 20, 21, 23, 25, 30, and 35 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"]. This rejection is traversed. According to MPEP 2131, to anticipate a claim, a reference must teach all elements of the claim. Kwee fails to meet this test.

Kwee's Hydrogel Contains Free Aqueous Phase

Presently pending claims 1 and 35 recite a colloid which is substantially free from a free aqueous phase. The Office Action alleges at page 2 that Kwee describes a composition that "does not contain *any free aqueous phase other than* the water that forms a part of the hydrogel" (Emphasis added). Thus the Examiner construes Kwee to describe a hydrogel that includes a free aqueous phase. For at least this reason, Applicants submit that Kwee does not anticipate independent claims 1 and 35, which include a colloid that is substantially free from a free aqueous phase.

Kwee Not Shown To Disclose The Claimed Degradation Rate

As recited in presently pending independent claims 1 and 35, the colloid can have an *in vivo* degradation time of less than one year. The Office Action at page 3 asserts that the dextrin described by Kwee reads on the polysaccharide described in the instant application, and concludes that Kwee therefore anticipates the presently pending claims.

The test for inherency requires the Action to show that the presently claimed degradation rate ***must*** flow as a natural consequence from the technological constraints of Kwee.

Yet this has not been shown. In fact, the instant specification at page 13, lines 4-7 and page 20 lines 7-9 teaches that various factors may effect degradation characteristics. Clearly, all polysaccharides do *not* have the same degradation rate. Accordingly, it is improper to conclude that an *in vivo* degradation time of less than one year is inherent to Kwee's dextrin.

The Office Action relies heavily on the doctrine of inherency to support the novelty rejection. This is likely because Kwee is a very brief patent, and provides only a limited description of hydrogels. There are no teachings that explicitly describe the presently pending claims.

Response to Arguments

At page 5, the Office Action asserts that claim 1 of Kwee does not state two separate phases, because claim 2 describes a separate compartment for water. Applicants disagree. It is not relevant whether Kwee's claim 1 requires water as a limitation. Kwee's claim 1 explicitly states that the claimed preparation when mixed with "water" becomes a highly viscose syringeable hydrogel. Kwee's claim 1 also recites a polymer that is insoluble or sparingly soluble in "water" but having the capability of swelling in "water." Further, claim 1 recites a water-soluble thickening agent [...] present in an amount sufficient to prevent separation of "water" from said hydrogel.

Applicants are pointing out that the resulting composition, *when prepared with water* according to the instructions provided in Kwee, contains two distinct phases: a water-soluble component (i.e. aqueous phase) and a water-insoluble component (i.e. non-aqueous phase). Both the water-soluble component and the water-insoluble component are recited in Claim 1 of Kwee. As explained in the **Osawa Rule 132 Declaration** (attached), Kwee describes a two-phase system that includes an aqueous phase and a water-insoluble phase.

Moreover, Kwee should not be construed to include only a single phase, because Claim 2 of Kwee discusses a first compartment with a swellable polymer and a second compartment with water, wherein either or both compartments contain a thickening agent and a drug. If Kwee's hydrogel preparation were construed as having only a single nonsoluble phase, as suggested by the Office Action, the preparation could not deliver a drug contained in the water compartment as described in Claim 2.

At page 5, the Office Action says that "[t]he absorbing agent of Kwee is present only to absorb excess water separated out of hydrogel." This interpretation is inconsistent with what Kwee actually describes in claim 1, where the thickening agent prevents separation of water from the hydrogel (col. 4, lines 25-26). There is a difference between absorbing water that is separated out of a hydrogel, and preventing water from becoming separated from the hydrogel in the first place. What is more, this interpretation appears to conflate the hydrogel of Kwee with the swellable polymer of Kwee. Applicants submit that the two terms are not synonymous: Kwee's hydrogel includes a combination of the swellable polymer and the thickening agent.

As noted in the **Osawa Rule 132 Declaration** (attached), Kwee's preparation involves two distinct phases: a water soluble phase, and a water insoluble phase. Kwee's thickening agent prevents water from being expressed first upon extrusion under pressure, resulting in co-extrusion of the two phases rather than preferential extrusion of water. Hence, Kwee's two distinct phases do not become physically separated during extrusion.

At page 5, the Office Action says that the water-soluble thickening agent is ***not part of*** the swollen polymer (emphasis added). Applicants agree. These are distinct components, both of which are contained in Kwee's hydrogel. Hence, the Office Action's observation supports the finding that Kwee's hydrogel preparation involves two distinct phases: the thickening agent and the swellable polymer.

At page 5, the Office Action further notes that Kwee's water-soluble thickener acts to absorb water that is not absorbed by the swellable polymer. Yet any such absorbtion would not negate the presence of a free aqueous phase. Applicants submit that a water-soluble thickener that absorbs water results in a free aqueous phase. As noted in Kwee at col. 1, lines 35-40, previously known gels were problematic because, when placed under pressure, water became separated from the gel thus rendering the gel unsyringeable. Kwee describes an attempt to remedy this by adding a water-soluble component, which provides *a water soluble phase* in the gel that is *not separated from* the gel when under pressure. For at least this reason, Kwee fails to anticipate presently pending independent claims 1 and 35, which recite a colloid that is substantially free from a free aqueous phase.

At page 5, the Office Action alleges that col. 3, lines 16-28 of Kwee support the position that the hydrogel does not have excess water due to the presence of the thickening agent. Applicants disagree. Nowhere does Kwee describe a problem with "excess" water. Kwee simply discusses the addition of the thickening agent to prevent water from separating from the hydrogel when under pressure, so that the hydrogel can be syringed.

At page 5, the Response asserts that "the insoluble polymer forms a hydrogel alone, without a need for the water-soluble thickener and hence the aqueous colloid is made of the swollen polymer alone." This suggestion is antithetical to Kwee's approach. Kwee's preparation in fact needs the thickener. As noted above, Kwee reports that if a hydrogel contains swollen polymer alone, without the water-soluble thickener, then it is not syringeable as desired. Moreover, Kwee's swellable polymer does not become physically separated from the thickening agent during syringing, and the thickening agent provides a free aqueous phase. Thus, Kwee's swellable polymer is not "substantially free from a free aqueous phase" as recited in the claims of the Application. For this reason, the swollen polymer alone as described by Kwee would not anticipate the presently pending claims, which recite an extrudable and fragmented single phase aqueous colloid. Put simply, neither Kwee's swellable polymer component nor Kwee's thickener, taken alone, is substantially free from a free aqueous phase.

At page 6, the Response argues that Applicants have defined the term "hydrogel" as comprising a single aqueous phase colloid, thus allowing for additional components such as thickening agents of Kwee to be present. This observation is not relevant. The presently pending claims recite the term "colloid" but not the terms "hydrogel" or "comprising." Hence, the Office Action is focusing on terms that are not recited in the claims. If the rejection under 35 U.S.C. §102 is maintained, it must be shown that Kwee discloses each and every *claim* element.

Based on the foregoing, Applicants submit that Kwee does not anticipate presently pending independent claims 1 and 35. Claims 20, 21, 23, 25, and 30 depend directly or indirectly from claim 1, and therefore are allowable as depending from an allowable base claim, as well as for the novel combination of elements they recite. Withdrawal of this rejection is respectfully requested.

Second Rejection Under 35 U.S.C. §102 (New Rejection; Office Action page 8)

¶(none provided). Claims 1, 19-21, 24, and 28 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent No. 4,424,208 to Wallace et al. ["Wallace"]. This rejection is traversed. According to MPEP 2131, to anticipate a claim, a reference must teach all elements of the claim. Wallace has not been shown to meet this test.

The Office Action at page 8 states that Wallace's "final hydrogel comprises a crosslinked gel and fibrous gel, which meets the claim limitation "substantially free of a free aqueous phase." This analysis is cryptic and confusing. There is no explanation as to how or why a crosslinked gel and a fibrous gel would be substantially free of a free aqueous phase. If this assertion is maintained, clarification is respectfully requested.

The Office Action at page 8 also states that Wallace describes the same process that is described in the instant specification at page 34, example 9 and therefore the claim terms "single phase aqueous colloid" are anticipated, and all of the other claim elements are inherently disclosed in Wallace. Applicants cannot agree.

At col. 4, line 31 to col. 5, line 9, Wallace describes the preparation of fibrous collagen, cross-linked collagen gel particles, and implant materials. In brief, the fibrous collagen is prepared as a dispersion, and the cross-linked collagen gel particles are prepared as a homogenized preparation. The fibrous collagen and cross-linked collagen gel particles are mixed and placed in sterile syringes. The Office Action says this is the same process that is disclosed in the Application at page 34, Example 9. As noted in the **Osawa Rule 132 Declaration** (attached), this conclusion is improper for at least the following reasons. First, this Wallace process involves collagen, whereas Example 9 involves gelatin. Second, this process described by Wallace involves adding gel to a 0.4% by weight solution of glutaraldehyde and allowing a one hour reaction. In contrast, Example 9 involves a glutaraldehyde treatment in a far more dilute glutaraldehyde solution that is processed overnight. Third, this Wallace process involves a phosphate buffer wash followed by centrifugation. In contrast, Example 9 involves an alcohol rinse, and centrifugation is not mentioned.

Hence, it has not been shown that Wallace teaches or suggests a single phase aqueous colloid which is substantially free from a free aqueous phase, as presently claimed.

Accordingly, presently pending claim 1, as well as dependent claims 19-21, 24, and 28 have not been shown to lack novelty. Withdrawal of this rejection is respectfully requested.

First Rejection Under 35 U.S.C. §103

¶2. Claims 19, 24, 31, 32, and 36 were rejected under 35 U.S.C. §103(a) as allegedly obvious over U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"]. This rejection is traversed.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited reference must teach or suggest all the claim elements. As noted above, Kwee fails to teach or suggest each and every element of presently pending independent claim 1, and for many of the same reasons, Applicants submit that Kwee fails to teach or suggest each and every element of presently pending independent claim 36, which recites a single phase aqueous colloid that is substantially free from a free aqueous phase.

Claims 19, 24, 31, and 32 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. For at least these reasons, the rejection must be withdrawn.

Moreover, the Office Action at page 3 acknowledges that Kwee does not explicitly teach the elements of these claims. Many of the obviousness arguments of the Office Action are conclusory, however, and do not support a proper §103 rejection. For example, presently pending claim 19 indicates the colloid can have a subunit size in the range from 0.01 mm to 5 mm. The Office Action does not address this claim element other than to say that "an appropriate particle size" would be obvious. This reasoning is perfunctory. If the rejection is maintained, Applicants respectfully request an explanation as to *why* the presently claimed subunit size would be obvious.

Second Rejection Under 35 U.S.C. §103

¶3. Claims 26-29, and 33 were rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 4,818,517 to Kwee et al. in view of U.S. Patent No. 4,837,285 to Berg et al. ["Berg"]. Applicants traverse this rejection.

MPEP 2143 requires that to establish a *prima facie* case of obviousness, among other things, the cited references when combined must teach or suggest all the claim elements.

As noted above, Kwee fails to teach or suggest each and every element of presently pending independent claim 1. Berg fails to remedy the deficiencies of Kwee, because Berg fails to teach or disclose a single phase aqueous colloid which is substantially free from a free aqueous phase as presently claimed.

Claims 26-29 and 33 depend either directly or indirectly from claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite. Withdrawal of this rejection is respectfully requested.

Third Rejection Under 35 U.S.C. §102 (New Rejection; Office Action page 9)

¶4. Claim 34 was rejected under 35 U.S.C. §102(b) as allegedly anticipated by Wallace as applied to claims 1, 19-21, 24, and 28 above, and further in view of U.S. Patent No. 6,110,484 to Sierra et al. ["Sierra"]. This rejection is traversed.

As an initial matter, it is unclear whether the Office Action intends to rejected claim 34 under §102 or §103. Because MPEP 2131 clearly states that a claim is anticipated under §102 only if each element is described in a *single* reference, for the sake of compact prosecution Applicants assume that the Office Action intended to rejected claim 34 under §103, because the rejection is based on the combination of *two* references: Wallace and Sierra. If this is incorrect, clarification is respectfully requested.

As noted above, it has not been shown that Wallace describes a "single phase aqueous colloid" having any of the characteristics recited in the claim. Moreover, it has not been shown that replacing the collagen of Wallace with the gelatin of Sierra would provide such characteristics, or why the artisan would expect such a result. The Office Action simply states that "Sierra suggests both collagen and gelating gels as equivalent in wound healing or tissue remodeling." However, the Office Action does not indicate where in Sierra this is mentioned.

To the contrary, Sierra appears to suggest that in some cases they are not equivalent, because Sierra reports that "matrix materials" may include collagen, but that porosifying agents may include "gelatin." See col. 4, lines 5-36. Because the combination of Wallace and Sierra has not been shown to teach or suggest each of the elements of presently pending claim 34, and because the Office Action has not explained why the artisan would be motivated to combine Sierra with Wallace or why the artisan would have a reasonable expectation of success of achieving the presently claimed colloid with such a combination, Applicants submit that it has not been shown that claim 34 is obvious in view of the proposed combination. Withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

/Nathan S. Cassell/

Nathan S. Cassell
Reg. No. 42,396

TOWNSEND and TOWNSEND and CREW LLP
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Attachment:
Rule 132 Declaration of A. Edward Osawa (with C.V.)

61013687 v1

I hereby certify that this correspondence is being filed via EFS-Web with the United States Patent and Trademark Office on July 5, 2007.

TOWNSEND and TOWNSEND and CREW LLP

By: /Nina L. McNeill/
Nina L. McNeill

PATENT
Docket No.: 017067-002040US
Client Ref. No.: WMFUS 5869(4)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

DONALD G. WALLACE et al.

Application No.: 09/553,969

Filed: April 21, 2000

For: FRAGMENTED POLYMERIC COMPOSITIONS AND METHODS FOR THEIR USE

Confirmation No.: 6560

Examiner: CHANNAVAJJALA, Lakshmi Sarada

Art Unit: 1615

DECLARATION UNDER 37 C.F.R. §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

I, A. Edward Osawa, state as follows.

1. My present position is Director, Research at Baxter Healthcare Corporation. The assignee of the above captioned application is Fusion Medical Technologies, Inc., which was purchased by Baxter Healthcare Corporation in 2002.

2. I received my Ph.D. from the Massachusetts Institute of Technology. My academic focus was Chemical Engineering. I have been an employee at Baxter Healthcare Corporation since 2002. I have participated in, or overseen, the design, execution, and interpretation of numerous experiments involving colloids. I regularly use colloid preparations and related technologies in the course of my employment. I am an inventor of several patents in this area and am familiar with the

scientific literature and practices of others in this field. A copy of my CV is attached as **Exhibit 1**.

3. I have read the above-captioned application ["Application"] and have followed its history.

4. I have reviewed the Office Action dated January 5, 2007 ["Office Action"]. I have also reviewed U.S. Patent No. 4,818,517 to Kwee et al. ["Kwee"] and U.S. Patent No. 4,424,208 to Wallace et al. ["Wallace"], which the Office Action is relying on in rejecting the presently pending claims of the Application.

5. Neither Kwee nor Wallace describe or suggest an extrudable fragmented biocompatible resorbable single phase aqueous colloid which is substantially free from a free aqueous phase, such as that described in presently pending claim 1 of the Application.

Kwee (U.S. Patent No. 4,818,517)

6. Kwee describes a two-phase system of a viscous aqueous phase and a water-insoluble phase, and does not teach or suggest an extrudable fragmented biocompatible resorbable single phase aqueous colloid which is substantially free from a free aqueous phase.

7. According to Kwee, previously known swellable polymer gels were problematic because, when placed under pressure, water became physically separated from the gel thus rendering the gel unsyringeable (col. 1, lines 35-40). In an attempt to remedy this, Kwee describes combining a thickening agent with a swellable polymer (col. 1, lines 45-48), and the thickening agent allows the combined composition

to be delivered through an injection syringe. Thus, Kwee's preparation involves two components: a thickening agent and a swellable polymer.

8. Kwee's preparation involves two phases: a water soluble phase, and a water insoluble phase. The water soluble phase, or aqueous phase, includes the thickening agent. The water insoluble phase, or non-aqueous phase, includes the swellable polymer. Thus, Kwee's preparation is a dual phase system, and is not a "single phase aqueous colloid" as stated in claims of the Application. Kwee's thickening agent prevents water from being expressed first upon extrusion under pressure, resulting in co-extrusion of the two phases rather than preferential extrusion of water. Put differently, Kwee describes two phases which are distinct, and that do not become physically separated during extrusion.

9. Taken alone, Kwee's thickening agent is not the same as the presently claimed colloid. Kwee's water soluble phase, which contains the thickening agent, is a free aqueous phase. For at least this reason, Kwee's thickening agent is different from a colloid that is "substantially free from a free aqueous phase" as recited in the claims of the Application.

10. Taken alone, Kwee's swellable polymer is not the same as the presently claimed colloid. As noted above, Kwee's swellable polymer does not become physically separated from the thickening agent during syringing, and the thickening agent provides a free aqueous phase. Thus, Kwee's swellable polymer is not "substantially free from a free aqueous phase" as recited in the claims of the Application.

11. Nowhere does Kwee describe a fragmented colloid as recited in claims of the Application. Relatedly, Kwee does not describe a colloid having a subunit size when fully hydrated in the range from 0.01 mm to 5 mm as recited in claims of the Application.

12. The Application describes compositions having a certain characteristics when fully hydrated. However, it does not necessarily follow that all polymers necessarily share the same characteristics. For example, page 13, lines 4-7 and page 20 lines 7-9 of the Application teach that various factors may effect degradation characteristics. Thus, all polysaccharides do not have the same degradation rate, such as a degradation time of less than one year as recited in claims of the Application.

13. For all these reasons, it is my opinion that there is no teaching or suggestion in the Kwee patent that Kwee's preparation is not an extrudable fragmented biocompatible resorbable single phase aqueous colloid which is substantially free from a free aqueous phase, as recited in claims of the Application. Moreover, Kwee does not describe a preparation that has a subunit size when fully hydrated in the range from 0.01 mm to 5 mm or an in vivo degradation time of less than one year as recited in claims of the Application.

Wallace (U.S. Patent No. 4,424,208)

14. At col. 4, line 31 to col. 5, line 9, Wallace describes the preparation of fibrous collagen, cross-linked collagen gel particles, and implant materials. In brief, the fibrous collagen is prepared as a dispersion, and the cross-linked collagen gel particles are prepared as a homogenized preparation. The fibrous collagen and cross-linked collagen gel particles are mixed and placed in sterile syringes. The Office Action says this is the same process disclosed in the Application at page 34, Example 9. I disagree, for at least the following reasons. First, this Wallace process involves collagen, whereas Example 9 involves gelatin. Second, this process described by Wallace involves adding gel to a 0.4% by weight solution of glutaraldehyde and allowing a one hour reaction. In contrast, Example 9 involves a glutaraldehyde treatment in a far more dilute glutaraldehyde solution that is processed overnight. Third, this Wallace process involves

a phosphate buffer wash followed by centrifugation. In contrast, Example 9 involves an alcohol rinse, and centrifugation is not mentioned.

15. The claims section of the Wallace patent show that the preparation is a two phase system which includes a suspension of collagen particles in an aqueous carrier. For example, claim 1 of Wallace states that the composition is a dispersion of collagen particulates within an aqueous phase. Thus, this is a two phase system having collagen particulates as a discrete phase from an aqueous phase serving as a carrier. The composition described by Wallace is not a single phase aqueous colloid substantially free from a free aqueous phase.

16. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature

07/02/07
Date

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EXHIBIT 1

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EDUCATION

1992 **MASSACHUSETTS INSTITUTE OF TECHNOLOGY, Cambridge, MA**
Ph. D., Chemical Engineering
Dissertation: "The Use of Fibrous Beds for the Chromatographic Separation of Proteins"
Minor Subject: Management
While completing dissertation, also served as Technical Coordinator for the MIT Biotechnology Process Engineering Center, organizing symposia and acting as graduate student liaison between the Center and its sponsoring companies.

1984 **UNIVERSITY OF SOUTHERN CALIFORNIA, Los Angeles, CA**
B.S., Chemical Engineering, *cum laude*
Awarded National Merit Scholarship.

EMPLOYMENT

1996-present **BAXTER HEALTHCARE CORPORATION /**
FUSION MEDICAL TECHNOLOGIES, Fremont, CA
(Baxter acquired Fusion in 5/02)
Director, Research
Responsible for technical development of "FloSeal"™, a novel hemostatic product used to stop problematic bleeding during surgery. Managed Manufacturing and Technical Operations departments. Directed development group efforts in establishing FloSeal manufacturing processes, formulations, process improvements and line extensions. Wrote and supervised execution of qualification and validation protocols for manufacturing process changes. Assisted in preclinical studies and in development of assays used to characterize product. Led project teams and design reviews. Provided supporting data for regulatory filings and patent applications.

1993-1996 **ARRIS PHARMACEUTICAL CORPORATION /**
KHEPRI PHARMACEUTICALS, South San Francisco, CA
(Arris acquired Khepri in 12/95)
Senior Scientist, Protein Biochemistry Group/ Process Development
Developed and scaled-up recovery and purification steps, including extraction, filtration, and chromatography, for a therapeutic recombinant membrane-associated protease. Created formulations for small molecule drug candidates for use in animal models. Devised protocols for recovering and assaying drug candidates from biological samples, and analyzed resulting pharmacokinetic data. Optimized purification methods for other recombinant proteins as targets for drug candidates. Isolated recombinant human chymase in sufficient quantity and purity to enable crystallographic studies.

1992-1993 **MERCK RESEARCH LABORATORIES, Rahway, NJ**
Engineering Associate, Bioprocess R&D, Natural Products Isolation Pilot Plant
Developed pilot-scale processes, including extraction, filtration, cell harvesting, centrifugation, crystallization, and chromatography, for isolating drug candidates and bioactive agents from natural products. Scaled up HPLC operations from laboratory unit to 15 cm diameter preparative columns.

PUBLICATIONS AND PRESENTATIONS

US Patent 6,706,690 "Hemoactive Compositions and Methods for their Manufacture and Use," C.J. Reich, A.E. Osawa, H. Tran, March 2004.

European Patent EP 0 927 053 B1, "Fragmented Polymeric Hydrogels for Adhesion Prevention and Their Preparation," D.G. Wallace, C.J. Reich, N.S. Shargill, F. Vega, A.E. Osawa, April 2003.

US Patent 6,066,325 "Fragmented Polymeric Hydrogels for Adhesion Prevention and Their Preparation," D.G. Wallace, C.J. Reich, N.S. Shargill, F. Vega, A.E. Osawa, May 2000.

US Patent 6,063,061 "Fragmented Polymeric Hydrogels for Adhesion Prevention and Their Preparation," D.G. Wallace, C.J. Reich, N.S. Shargill, F. Vega, A.E. Osawa, May 2000.

"Purification of pneumocandins by preparative silica gel high-performance liquid chromatography," A.E. Osawa, R. Sitrin, S.S. Lee, *J. Chromatography A*, **831**:217-225 (1999).

"Production of a crystallizable human chymase from a *Bacillus subtilis* system," M.E. McGrath, A.E. Osawa, M.G. Barnes, J.M. Clark, K.D. Mortara, and B.F. Schmidt, *FEBS Letters*, **413**:486-488 (1997).

"Pilot-scale harvest of recombinant yeast employing microfiltration: a case study," G. Russotti, A.E. Osawa, R.D. Sitrin, B.C. Buckland, W.R. Adams, S.S. Lee, *J. Biotechnol.*, **42**(3):235-46 (1995).

Presented papers at the AIChE Annual Meeting (Dec. 1988), ACS National Meetings (Sep. 1989, Apr. 1992), 10th Preparative Liquid Chromatography Conference (May 1993); presented posters at 6th Preparative Liquid Chromatography Conference (May 1989), NATO ASI on Chromatographic and Membrane Processes in Biotechnology (July 1990).

TRAINING

DMAIC – Green Belt (Baxter, 2005; class portion only)
Lean Manufacturing (Baxter, 2004)
Design of Experiments (American Chemical Society, 2001)
Patent Law for Managers, Engineers, and Scientists (Center for Professional Advancement, 2001)
Lyophilization Technology (Parenteral Drug Association, 2000)

PERSONAL

Moderately proficient in Japanese language.
Two-day champion on *Jeopardy!*
Interests include foreign languages, films, golf, volleyball.